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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,323	05/31/2005	Hiroaki Matsuno	259979US0PCT	7538

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/509,323	MATSUNO ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/23/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-4 and 10-15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/23/09 has been entered.

Receipt is acknowledged of the Amendments, Remarks and Terminal Disclaimer filed on 11/23/09, a Declaration filed on 12/14/09 and an IDS filed on 08/10/09. Claim 1 has been amended and new claim 15 has been added while no claims have been cancelled. Accordingly claims **1-4 and 10-15** are pending.

Terminal Disclaimer

The terminal disclaimer does **not** comply with 37 CFR 1.321(b) and/or (c) because:

37 CFR 1.321 (c)(3) requires that a TD "Include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting." [Emphasis added].
The words "legal title" do not include common ownership as to equitable title.

Accordingly, the terminal disclaimer filed on 11/23/09 has **not** been accepted. The terminal disclaimer has not been recorded.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dorigatti et al (WO 9320858).

Dorigatti et al teach bonding solutions for granular bone replacements are provided, comprising hyaluronic acid or hyaluronic acid derivatives such as hyaluronic acid esters and hyaluronic acid antibiotic salts in combination with natural or artificial bone granules. These solutions can be used in bone surgery (see abstract). Dorigatti et al disclose that one object of the invention is to provide a paste comprising a viscous solution of hyaluronic acid and/or hyaluronic acid esters or salts of hyaluronic acid in association with antibiotics used singly or in combination, and bone granules (see page 4). Example 36 discloses a formulation comprising hyaluronic acid and neomycin and polymixin.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Royer (US 6,391,336) *or* **Royer (US 6,630,486).**

Royer '336 and '486 both teach production and use of inorganic-polymer complexes for the controlled release of compounds including medicinals (see abstract). Certain formulations are prepared with the inorganic and some are prepared without the inorganic, such as formulation E in Table 1, which comprises hyaluronic acid and amikacin (an antibiotic).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellini et al. (US Pat. 6,251,876) in view of Collins et al. (US Pat. 6,096,728).

Bellini et al. disclose an autocross-linked **hyaluronic acid** (HA) containing intra- and inter chain ester bonds where autocross-linked HA can be synthesized from HA having a molecular weight in the range from 50 kDa to 5,000 kDa that is used to treat arthropathies (Column 3, lines 20-38). It is disclosed that the autocross-linked HA can also contain external esters by cross linking with mono or polyvalent alcohol (Column 5, lines 8-23). It is disclosed that the composition can include **an antibiotic** (Column 4, lines 6-9, Claim 4). Bellini discloses suitable antibiotics to include erythromycin, lincomycin, etc (see col. 8, lines 17-22).

Collins et al. disclose the combination of a drug substance and cross-linked hyaluronan gels and that the drug can be used to treat inflammatory conditions of a joint such as gentamicin, vancomycin and structurally related antimicrobials (Column 7, lines 10-19, Column 28, lines 31-38, Column 32, lines 34-50).

The claims are interpreted to include two embodiments (In light of the language of “and/or”). One embodiment requires a composition comprising an antibiotic and a hyaluronic acid. Various infections are considered “intended use” and are not given patentable weight in a product claim. Thus the above cited references meet all the limitations of the said claims. Bellini et al disclose hyaluronic acid in combination with an antibiotic. Collins et al disclose the specific antibiotic of claim 13.

It would have been obvious to one of ordinary skill in the art at the time the invention was made, given the general teachings of the formulations of Bellini et al

comprising a hyaluronic acid and active agents such as antibiotics, to have looked in the art for other and specific antibiotics for combination with the formulations of Bellini et al, as taught by Collins et al with reasonable expectation of successfully preparing a formulation that delivers the active agents to the site of action. In other words, the claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-4, 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyoshi et al (WO 0027405, as evidenced by its US 6,635,267) in view of Collins et al. (US Pat. 6,096,728).

Miyoshi et al 'US '267 teach a gel made of **hyaluronic acid alone** which is hardly soluble in a neutral aqueous solution and has fluidity enough to be easily ejectable from an injector (see abstract). The molecular weight of the HA to be used in the present invention is preferably within the range of from about $1x10^5$ to about $1x10^7$ Daltons (see col. 6, lines 6-10). The HA gel according to the invention can be solubilized through degradation by treatment under accelerating conditions for acid hydrolysis of

HA (see col. 6, lines 29-33). Miyoshi lacks disclosure on combining the HA gel with antibiotics. This deficiency is cured by Collins et al.

Collins et al. disclose the combination of a drug substance and cross-linked hyaluronan gels and that the drug can be used to treat inflammatory conditions of a joint such as gentamicin, vancomycin and structurally related antimicrobials (Column 7, lines 10-19, Column 28, lines 31-38, Column 32, lines 34-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, given the general teachings of the formulations of Miyoshi et al comprising a cross-linked hyaluronic acid gel and active agents, to have looked in the art for other and specific active agents such as antibiotics for combination with the formulations of Myioshi et al, as taught by Collins et al with reasonable expectation of successfully preparing a formulation that delivers the active agents to the site of action. In other words, the claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-4, 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawata et al (WO 0157093, as evidenced by its US 7,014,860) in view of Collins et al. (US Pat. 6,096,728).

Kawata et al teach production of hyaluronic acid gel which comprises keeping hyaluronic acid in water at a hyaluronic acid concentration of at least 5 wt% in the presence of an acid component in an amount at least equimolar with the carboxyl groups in the hyaluronic acid (see abstract). It is disclosed that "The present invention provides a hardly water soluble hyaluronic acid gel made of **hyaluronic acid alone** with transparency. The hyaluronic acid gel according to the present invention retains the structure of the biologically inherent hyaluronic acid by virtue of obviation of use of crosslinkers, and is excellently safe and biocompatible. Therefore, it is useful as a biomedical material such as an injection for treatment of arthrosis, an embolizing material, an injection for a soft tissue and an artificial vitreous body" (see col. 6, lines 22-30).

Kawata et al also discloses that the molecular weight of the HA to be used in the present invention is preferably within the range of from about $1x10^5$ to about $1x10^7$ Daltons (see col. 6, lines 62-67). The HA gel according to the invention can be solubilized through degradation by treatment under accelerating conditions for acid hydrolysis of HA (see col. 7, lines 31-36). Kawata et al lacks disclosure on combining the HA gel with antibiotics. This deficiency is cured by Collins et al.

Collins et al. disclose the combination of a drug substance and cross-linked hyaluronan gels and that the drug can be used to treat inflammatory conditions of a joint such as gentamicin, vancomycin and structurally related antimicrobials (Column 7, lines 10-19, Column 28, lines 31-38, Column 32, lines 34-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, given the general teachings of the formulations of Kawata et al comprising a cross-linked hyaluronic acid gel and active agents, to have looked in the art for other and specific active agents such as antibiotics for combination with the formulations of Kawata et al, as taught by Collins et al with reasonable expectation of successfully preparing a formulation that delivers the active agents to the site of action. In other words, the claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1-4 and 10-15** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 18-21 of U.S. Patent No. **7,014,860** in view of 6,096,728 (Collins et al). An obviousness-type double patenting rejection is appropriate because while the conflicting claims are not identical, the examined claims are not patentably distinct from the reference claims because the examined claims would have been obvious over the reference claims in view of 6,096,728 (Collins et al).

Here, instant claims are drawn to a composition comprising an antibiotic and a hyaluronic acid and/or a hyaluronic acid gel, wherein the hyaluronic acid gel is crosslinked hyaluronic acid made of hyaluronic acid having a weight average primary molecular weight greater than 800,000 wherein the hyaluronic acid gel is prepared by dissolving hyaluronic acid in an aqueous solution at an acidic pH with no crosslinkers to form the hyaluronic gel and wherein the antibiotic is added to the formed hyaluronic gel.

The reference claims are drawn to a biomedical material which contains a transparent gel consisting of hyaluronic acid or a salt thereof; a second acid or a salt thereof; and water; wherein the transparent gel does not contain any cross-linkers, and wherein the hyaluronic acid gel dissolves in a neutral aqueous solution.

The difference is that the reference claims do not recite or require the addition of an antibiotic to the gel. Collins et al remedies this deficiency. Collins et al teach a composition comprising hyaluronic acid and active agents such as antibiotics for effective drug delivery to the sites. It would have been obvious to one of ordinary skill in the art to have implemented the teachings of Collins et al on the addition of an antibiotic to the formulations of the reference claims with reasonable expectation of successful delivery of active agents to the desired site of action.

Claims **1-4 and 10-15** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. **6,635,267** in view of 6,096,728 (Collins et al). An obviousness-type double patenting rejection is appropriate because while the conflicting claims are not identical, the examined claims are not patentably distinct from the reference claims because the examined claims would have been obvious over the reference claims in view of 6,096,728 (Collins et al).

Here, instant claims are drawn to a composition comprising an antibiotic and a hyaluronic acid and/or a hyaluronic acid gel, wherein the hyaluronic acid gel is crosslinked hyaluronic acid made of hyaluronic acid having a weight average primary

molecular weight greater than 800,000 wherein the hyaluronic acid gel is prepared by dissolving hyaluronic acid in an aqueous solution at an acidic pH with no crosslinkers to form the hyaluronic gel and wherein the antibiotic is added to the formed hyaluronic gel.

The reference claims are drawn to a hyaluronic acid gel comprising water and hyaluronic acid, wherein the said hyaluronic acid is not in the form of a complex with cationic polymer and wherein the gel is auto cross-linked.

The difference is that the reference claims do not recite or require the addition of an antibiotic to the gel. Collins et al remedies this deficiency. Collins et al teach a composition comprising hyaluronic acid and active agents such as antibiotics for effective drug delivery to the sites. It would have been obvious to one of ordinary skill in the art to have implemented the teachings of Collins et al on the addition of an antibiotic to the formulations of the reference claims with reasonable expectation of successful delivery of active agents to the desired site of action.

Claims **1-4 and 10-15** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 24, 26 and 29 of U.S. Patent No. **6,638,538** in view of 6,096,728 (Collins et al). An obviousness-type double patenting rejection is appropriate because while the conflicting claims are not identical, the examined claims are not patentably distinct from the reference claims because the examined claims would have been obvious over the reference claims in view of 6,096,728 (Collins et al).

Here, instant claims are drawn to a composition comprising an antibiotic and a hyaluronic acid and/or a hyaluronic acid gel, wherein the hyaluronic acid gel is crosslinked hyaluronic acid made of hyaluronic acid having a weight average primary molecular weight greater than 800,000 wherein the hyaluronic acid gel is prepared by dissolving hyaluronic acid in an aqueous solution at an acidic pH with no crosslinkers to form the hyaluronic gel and wherein the antibiotic is added to the formed hyaluronic gel.

The reference claims are drawn to a composition comprising hyaluronic acid and a polymer wherein the process does not require presence of any cross-linkers, and wherein the hyaluronic acid gel dissolves in a neutral aqueous solution.

The difference is that the reference claims do not recite or require the addition of an antibiotic to the gel. Collins et al remedies this deficiency. Collins et al teach a composition comprising hyaluronic acid and active agents such as antibiotics for effective drug delivery to the sites. It would have been obvious to one of ordinary skill in the art to have implemented the teachings of Collins et al on the addition of an antibiotic to the formulations of the reference claims with reasonable expectation of successful delivery of active agents to the desired site of action.

Claims **1-4 and 10-15** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. **6,387,413** in view of 6,096,728 (Collins et al). An obviousness-type double patenting rejection is appropriate because while the conflicting claims are not identical, the examined claims are not patentably distinct from the reference claims because the

examined claims would have been obvious over the reference claims in view of 6,096,728 (Collins et al).

Here, instant claims are drawn to a composition comprising an antibiotic and a hyaluronic acid and/or a hyaluronic acid gel, wherein the hyaluronic acid gel is crosslinked hyaluronic acid made of hyaluronic acid having a weight average primary molecular weight greater than 800,000 wherein the hyaluronic acid gel is prepared by dissolving hgaluronic acid in an aqueous solution at an acidic pH with no crosslinkers to form the hgaluronic gel and wherein the antibiotic is added to the formed hyaluronic gel.

The reference claims are drawn to a gel comprising hyaluronic acid and a biomedical material which contains a gel consisting of hyaluronic acid or a salt thereof; wherein the gel does not contain any cross-linkers, and wherein the hyaluronic acid gel dissolves in a neutral aqueous solution.

The difference is that the reference claims do not recite or require the addition of an antibiotic to the gel. Collins et al remedies this deficiency. Collins et al teach a composition comprising hyaluronic acid and active agents such as antibiotics for effective drug delivery to the sites. It would have been obvious to one of ordinary skill in the art to have implemented the teachings of Collins et al on the addition of an antibiotic to the formulations of the reference claims with reasonable expectation of successful delivery of active agents to the desired site of action.

Response to Arguments

Applicant's arguments filed 11/23/09 have been fully considered but they are not persuasive.

Applicant argues that Bellini requires additional substances to activate the HA, e.g. metal salts. Applicants sate that "it is an error to disregard express limitations in the claims". Then Applicant argues that while the instant claims require no crosslinkers, "Bellini includes them and Examiner has put forth no reasoning based on evidence why the Bellini gels would inherently be the same".

This is not persuasive because Examiner clearly pointed out in the last Office action, that the claim language employs the term "and/or", which renders the claim obvious over art for its teaching of hyaluronic acid. Bellini is relied upon for its hyaluronic acid, and not for its teaching of hyaluronic acid gels. The instant claim 1 is drawn to a composition comprising an antibiotic and a hyaluronic acid and/**or** a hyaluronic acid gel". The term and/or allows for the scope to be a formulation comprising an antibiotic and hyaluronic acid. The limitation "wherein the hyaluronic acid gel is crosslinked…." does not apply to hyaluronic acid. Thus Bellini teaching hyaluronic acid and a medicine such as an antibiotic meets the claim limitations. Examiner did not rely on inherency, but a simple teaching of the claim limitation by prior art. Furthermore, the claim uses the open language of "comprising" as the transition term. Thus the claim does not exclude other components, such as a metal salt taught by Bellini.

Applicant also argues extensively that Bellini teaches hyaluronic acid gels that contain lactonic bonds. Again Bellini was relied upon for its teaching of hyaluronic acid,

not hyaluronic acid gel. Applicant's arguments are not commensurate with scope of claims.

With regards to the rejection of claims under obviousness Double Patenting over Miyoshi and Kawata ('267 and '860 patents), Applicant argues that, the instant claims require HA gels that are intended to hold the antibiotic and release the antibiotic by its biodegradation. In contrast, Applicant continues, the HA gels of Miyoshi and Kawata are transparent HA gels with fluidity, good biocompatibility and improved *in vivo* persistency and not designed to hold antibiotics and release antibiotics by their biodegradation.

The arguments are not commensurate with the scope of claims. It is noted that neither sets of claims are drawn to a method of drug release, but to a formulation comprising a hyaluronic acid and an active agent. Thus it has been shown that the reference claims would have rendered the instant claims obvious.

Declaration

A declaration by one of the inventors, Masamichi Hashimoto, filed on 12/14/09 has been fully considered but is found not be persuasive in obviating the rejection of claims over Bellini et al. Applicant states that "the hyaluronic acid gels of the present invention, prepared in the manner as set forth in Example 1 of the specification, differs from the cross-linked hyaluronic acid of U.S. Patent 5,676,964 and Bellini in that:

A) the hyaluronic acid gel of the present invention does not have lactonic bonds whereas Bellini's has lactonic bonds; and

B) the degree of esterification of the Applicant's hyaluronic acid gel is about 0.15, whereas the degree of esterification of the cross-liked hyaluronic acid of U.S. Patent 5,676,964 and Bellini is from 1 to 60%, preferably 5 to 30%".

This is not found persuasive because as recited above, the Bellini reference was relied upon for its teaching of hyaluronic acid and not hyaluronic acid gel. Thus Applicants arguments are not considered commensurate with the scope of claims. Instant claims are drawn to a formulation comprising an antibiotic and a hylauronic acid. Bellini et al meets all the claimed limitation.

Furthermore, Applicants arguments regarding the process of making the gels is not persuasive because According to MPEP 2113 [R-1], product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. Therefore, claims are taught by the cited references.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616